IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NICOLE RADICE,	:	
	:	
Plaintiff,	:	
	:	**C.A. No.:**
v.	:	
	:	**TRIAL BY JURY DEMANDED**
BOSTON SCIENTIFIC CORPORATION,	:	
	:	
Defendant.	:	

COMPLAINT

JURISDICTION AND VENUE

1. Jurisdiction in this Court is based on the diversity of citizenship of the parties pursuant to 28 U.S.C. §1332(a)(2).

2. Venue in this Court is proper pursuant to 28 U.S.C. §1391(b).

3. The matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

THE PARTIES

4. Plaintiff Nicole Radice ("Ms. Radice") is and was, at all times relevant to this action, a resident of the State of Connecticut.

5. Defendant Boston Scientific Corporation (hereafter referred to as "BSC") is a corporation organized and existing under the laws of the State of Delaware. It may be served by serving its registered agent for service of process at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

6. At all times relevant hereto, BSC acted through its officers, agents, servants, and employees, or those associated with any relevant subsidiary or related entity, and is therefore liable for their conduct pursuant to the doctrine of *respondeat superior*.

THE PRECISION FAMILY OF NEUROSTIMULATOR DEVICES

7. At all times relevant hereto BCS designed, manufactured, marketed, distributed, and/or sold a Precision Spectra WaveWriter Model SC-1160, Serial No. 358842, that was surgically implanted into Ms. Radice's body (hereafter referred as to the "SCS device") on May 17, 2019.

8. The SCS device is among the Precision family of neurostimulator devices approved for commercial distribution by the U.S. Federal Food and Drug Administration ("FDA") under PMA (Premarket Approval) No. P030017 pursuant to the authority granted to the FDA by Congress under the Medical Device Amendments of 1976, 21 U.S.C. §360, *et seq.* (hereafter referred to as the "MDA"). These neurostimulator devices are designated by the FDA as Class III medical devices within the meaning of the MDA.

9. On or about May 14, 2003 BSC filed an original PMA application for the approval of the Precision[tm] spinal cord stimulation ("SCS") system (hereinafter referred to as the "Precision System"), to be used as an aid "in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable back pain and leg pain".

10. On or about April 27, 2004 the FDA granted BSC's PMA application for the commercial distribution of the Precision System. The FDA's approval was accompanied by, and made subject to, certain "Conditions of Approval". A true and correct copy of the PMA approval letter and Conditions of Approval are appended hereto as Exhibit A.

11. The aforementioned approval letter and Conditions of Approval set forth the following relevant requirements:

"A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidents of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification".

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A "Special PMA Supplement—Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2).... These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement—Changes Being Effected".

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POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA..... The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changed required to be reports to FDA under 21 CFR 814.39(b).
2.

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ADVERSE REACTION AND DEVICE DEFECT REPORTING

As provided by 21 CFR 814.82(a)(9), FDA had determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "adverse reaction report " or "device defect report"...within 10 days after the applicant receives or has knowledge or information concerning:

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3. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributed to the device and:
   a. has not been addressed by the device's labeling; or,
   b. has been addressed by the device's labeling but is occurring with expected severity or frequency.

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REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices...report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction would occur.

12. The initial labeling for the Precision System, submitted by BSC and approved by the FDA, included a Physician Implant Manual. A true and correct copy of the Manual is appended hereto and incorporated herein as Exhibit B to this Complaint.

13. On or about May 6, 2010 the FDA approved a supplemental labeling change to the Precision System under P030017/S098. The approved change was for the consolidation of three separate instruction manuals—the Physician Implant Manual, the Physician Lead Manual and the Physician Surgical Lead Manual—into a single manual to be thereafter titled the Precision System Clinical Manual.

14. On or about May 7, 2012 BSC filed with the FDA a Supplement application—P030017/S134—for approval of the Precision Spectra System. The stated reason for this Supplement was to introduce a new neurostimulation system with changes to the design, components, specifications, and materials used for the Precision System. The new Spectra system included the use of a new Model SC-1132 Implantable Pulse Generator (IPG) and a Model NM-6210 USB Power Supply. The new system was to be marketed under the trade name Precision Spectra System and was indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. The Supplement was approved by the FDA on December 21, 2012.

15. On or about December 16, 2016 BSC filed with the FDA a Supplement application—P030017/S271—to rebrand the Precision Spectra System under the name Spectra WaveWriter SCS System (hereafter the "Spectra WaveWriter"). BSC also sought to update the

System's firmware/software to support new features, but no changes were made to the hardware or material of any components used in the existing system. The FDA approved the Supplement application on March 13, 2017.

16. A number of subsequent Supplement applications filed by BSC with the FDA addressed matters concerning the battery component of the Spectra WaveWriter IPG. For example on August 21, 2013 BSC filed a Supplement application—P030017/S177—to update the test software for checking the battery profile of the IPG. On or about February 11, 2015 BSC filed a Supplement application—P030017/S214—to introduce new battery test equipment. On or about November 2, 2017 BSC filed a Supplement application for approval of a modification to the IPG firmware to improve the accuracy of the temperature sensor reading. The data and need for these Supplement applications resides solely in the possession of BSC.

17. At no time between the introduction of the Precision system in 2004 and May 17, 2019 did BSC make or seek approval of any changes to its labeling that are relevant to the claims in this action.

18. On May 17, 2019 the SCS device was surgically implanted into Ms. Radice's body. Accompanying the device was a circa 2017 Precision^{tm} Spinal Cord Stimulator System Clinician Manual for use by Ms. Radice's physicians. A true and correct copy of the Clinician Manual is appended hereto and incorporated herein as Exhibit C. Table 1 of the Manual, at page 6 of 69, summarizes the risks associated with all spinal cord neurostimulators systems based on a sample of 880 patients. Lead migration was identified as an adverse event that occurred in 19.9% of the sampled cases. Insufficient pain control and over/under stimulation occurred with 5.2% of the patients. There is no mention of uncomfortable or painful IPG heating/overheating/electrical shocks. As for the safety of the Precision System itself, the Manual pointed to a sample of 26

patients who had received implants prior to January 15, 2004. According to Table 2 of the Manual, also at page 6 of 69, there was 1 documented instance of "lead migration" resulting in surgery to reposition and replace the lead and 1 documented instance of "output malfunction" for which the device itself was surgically replaced. The Manual provides no information as to the Precision System's clinical experience for safety between January 15, 2004 and it publication in 2017. Nor were Ms. Radice's physicians provided with any additional labeling between the publication of the 2017 Clinician Manual and May 17, 2019 when Ms. Radice received the SCS device.

19. As required by the FDA's regulations, the 2017 Clinician Manual given to Ms. Radice's physicians listed contraindications, warnings, precautions, and adverse effects associated with the implantation and use of the SCS device. The only reference to IPG heating/overheating/electrical shocks is an warning against charging the IPG while sleeping or without using a Charging Belt or adhesive patch. As for the risk of lead migration, the Manual states that "**[i]n some instances** a lead can move from its original location…", resulting in the loss of stimulation at the intended pain site. With regard to the movement or migration of the IPG itself, the Manual states that "[o]ver time, the stimulator may move from its original position". There is no reference in the Manual to any risk of electrical shocks occurring with or without stimulation.

CUSTOMER COMPLAINTS AND RELEVANT RECALL HISTORY

20. The Precision System neurostimulator devices have been the subject of patient complaints and relevant recall campaigns since its introduction in 2004.

21. On November 22, 2004 BSC initiated a Class 3 Device Recall after a patient suffered a burn injury while sleeping. Patient notices were sent by FedEx or U.S.. Mail to all clinicians regarding a labeling addenda to address this circumstance. Upon information and belief

this labeling addenda was later incorporated into the Clinician Manual appended hereto as Exhibit C.

22. On September 22, 2008 BSC initiated a Class 2 Device Recall due to patients receiving second and third degree burns at the site of the IPG while charging the device. The report of these occurrences caused BSC to voluntarily recall its first generation charging device in favor of a second generation charger. Additionally, a letter with corrected instructions was sent to all of the affected "customers".

23. A review of the FDA's MAUDE database reveals that for the Precision System there were thirteen (13) Adverse Event Reports (AERs) relating to insufficient or ineffective pain relief/stimulation in 2017; seventy-three (73) such AERs in 2018 (partial year only); and one hundred eleven (111) such AERs in 2019 (partial year only). Most if not all of these adverse events resulted in the surgical explanation or replacement of the IPG. Because the MAUDE database is limited to 500 AERs per medical device for each calendar year it is reasonable to conclude that there were in fact more such adverse events from 2017 to 2019.

24. A review of the FDA's MAUDE database further reveals that for the Precision Spectra System the FDA received twenty-five (25) AERs relating to warmth/heating/burning with or without charging at the IPG site in 2017; nineteen (19) such AERs in 2018 (partial year only); and fifteen (15) such AERs in 2019 (partial year only). Most if not all of these adverse events resulted in the surgical explanation or replacement of the IPG. Because the MAUDE database is limited to 500 AERs per medical device for each calendar year it is reasonable to conclude that there were in fact more such adverse events from 2017 to 2019.

25. A review of the FDA's MAUDE database further reveals that for the Precision Spectra System there were eight (8) AERs relating to electrical shocks or sudden severe

overstimulation in 2017; six (6) such AERs in 2018 (partial year only); and eleven (11) such AERs in 2019 (partial year only). Most if not all of these adverse events resulted in the surgical explanation or replacement of the IPG. Because the MAUDE database is limited to 500 AERs per medical device for each calendar year it is reasonable to conclude that there were in fact more such adverse events from 2017 to 2019.

26. A review of the FDA's MAUDE database further reveals that for the Precision Spectra System there were seventeen (17) AERs relating to migration or repositioning of the IPG inside or outside of the surgically-created pocket in 2018 (partial year only) and eight (8) such AERs in 2019 (partial year only). Most if not all of these adverse events resulted in the surgical explanation or surgical repositioning of the IPG. Because the MAUDE database is limited to 500 AERs per medical device for each calendar year it is reasonable to conclude that there were in fact more such adverse events from 2017 to 2019.

THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

27. The FDA's initial approval letter for the Precision family of neurostimulator devices [and therefore the SCS device] states that "The sole distribution and use of this device are restricted to prescription use in accordance with 21 C.F.R. 801.109". Subsections (c) and (d) of §801.109 provide as follows:

> "(c) Labeling on or within the package from which the device is to dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, **and any relevant hazards**, contraindications, side effects, **and precautions** under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it was intended, including all purposes for which it is advertised or represented....
> (d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration, **and any relevant hazards**, contraindications, side

> effects, **and precautions** under which practitioners licensed by law to employ the device can use the device safely and for the purpose for which it was intended, including all purposes for which it is advertised or represented…". [emphasis added].

21 C.F.R. §814.39(a) requires that a manufacturer of a medical device submit a supplemental PMA for any proposed labeling changes that affect the safety of the device. Subsection (d) of §814.39 further provides that after the FDA approves a PMA the applicant may put into effect any change in labeling "…to reflect newly acquired information that enhances the safety of the device…" before the supplement has been approved, including "labeling changes that add or strengthen a …warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association". See 21 C.F.R. §814.39(d)(1) and (2)(i). These regulatory requirements were mandated by the Conditions of Approval for the Precision family of devices, including the Precision model IPG, but there is no indication that BSC complied with or took action to supplement its labeling to address the relevant hazards at issue in this action.

28. Similarly, the Conditions of Approval issued by the FDA to BSC required compliance with 21 C.F.R. §814.82(a)(9) which calls for the submission of an Adverse Reaction Report or Device Defect Report to the FDA within ten days after BSC received or acquired knowledge of information concerning "…any adverse reaction…, injury, …that is attributable to the device and…has not been addressed by the device's labeling…". BSC has failed to truly and adequately submit all the reports required by their provisions.

29. Federal regulations also impose on the manufacturer of a medical device such as BSC certain reporting requirements. 21 C.F.R. §803.1 states that the purpose of the Medical Device Reporting ("MDR") requirements is to "…help us to protect the public health by helping ensure that devices are not adulterated or misbranded and are safe and effective for their intended use". Section 803.10(c) requires a manufacturer like BSC to "[s]ubmit reports of individual

adverse events no later than thirty (30) calendar days after the day that you become aware of a death, serious injury, or malfunction…" and to "[s]ubmit supplemental reports if you obtain information that you did not submit in an initial report". Section 803.50 sets forth similar reporting requirements. Again BSC had failed to truly and completely submit all the reports required by their provisions.

30. 21 C.F.R. §806.10 requires a manufacturer like BSC to submit a report of any correction to a device that is needed to reduce a risk to health posed by the device. There is no indication that BSC had ever submitted a corrective report to address the relevant hazards at issue in this action.

31. 21 C.F.R. §820.198 mandates that each manufacturer such as BSC "maintain procedures for receiving, reviewing, and evaluating complaints…" and if any complaint represents a reportable adverse event under 21 C.F.R. §803 to communicate with the complainant upon completion of its investigation. Ms. Radice has never received any such communication from BSC.

32. Upon information and belief the FDA publishes reports of adverse events and MDRs in a searchable database for use by the general public including physicians and patients. This reporting serves to notify the public of a potential problem with a device so the informed person can avoid the hazard or develop a solution to address it.

33. Once the SCS device was approved for commercial distribution through the PMA process, BSC also became bound by the "good manufacturing practices" ("GMP") requirements found in 21 C.F.R. §820.1-820.198. §820.90(a) requires that each manufacturer "…establish and maintain procedures to control product that does not conform to specified requirements". §820.100(a)(3) requires each manufacturer to "[i]dentify the action(s) needed to correct and

prevent reoccurrence of nonconforming product and other quality problems…". Ms. Radice received a non-conforming device as set forth below.

MS. RADICE'S EXPERIENCE WITH THE SCS DEVICE

34. In 2004 Ms. Radice suffered an injury to her low back when a drunk driver struck her vehicle in a parking lot. She was initially diagnosed with herniated discs at three lumbar levels from L3-L4 to L5-S1. Over the ensuing years Ms. Radice developed progressively worsening degenerative disc disease throughout her lumbar spine, which in turn caused progressively worsening back pain as well as numbness and weakness in both her legs.

35. Between 2004 and 2016 Ms. Radice tried a variety of conservative treatment modalities under the care of her long-time pain management physician—Dr. David Kloth. This included medications, physical therapy, epidural steroid injections, and radiofrequency ablation procedures. Unfortunately, none of these conservative forms of treatment helped to reduce or resolve her pain.

36. In 2016 Ms. Radice was informed for the first time that she had a tethered spinal cord. She was referred to a specialist in Rhode Island who on September 14, 2016 performed surgery to "detether" the spinal cord together with a traditional laminectomy to address the herniated discs. Unfortunately, the surgery only made matters worse. Ms. Radice woke up in the recovery room with excruciating low back pain that radiated down into both legs. She remained hospitalized in Rhode Island for approximately 1 week until her condition was stable enough to return to her home in Norwalk, Connecticut.

37. Upon returning home Ms. Radice consulted with several different physicians who were unable to assist her with her ongoing disabling pain. Eventually she returned to see Dr. Kloth on May 8, 2018. At that visit Ms. Radice inquired about a spinal cord stimulator device as a

possible treatment option. Dr. Kloth noted that he had been holding off on assessing her as a candidate for a neurostimulator device as he wanted to make sure there was no other "definitive surgical treatment" that could be offered, but none of the doctors she had seen had recommended further surgery. Given that Ms. Radice's status quo was "in a bad place" Dr. Kloth gave her some stimulator materials to read and told her he would discuss it with her in more detail on her next visit.

38. On June 5, 2018 Ms. Radice reported to Dr. Kloth that she had reviewed the information on the spinal cord stimulator and wanted to proceed with a trial. It was Dr. Kloth's assessment that "the large majority" of her symptoms were "neuropathic" in origin. The plan as recorded by Dr. Kloth in his progress note was to obtain approval for a trial of a Boston Scientific spinal cord stimulator with two leads. He also answered "multiple questions" from Ms. Radice and her significant other regarding the planned trial.

39. On December 3, 2018 Ms. Radice received approval from her insurance company to proceed with the spinal cord stimulator trial. The trial was initiated by Dr. Kloth on December 10, 2018 and continued for five days through December 14, 2018. At the end of the trial Ms. Radice reported 70% to 80% improvement in her leg pain and complete resolution of the light touch sensitivity in her left leg. She did not feel as much improvement in her low back pain, even at "fairly high amplitudes", but both she and Dr. Kloth agreed there was enough improvement to move forward with a permanent implantation.

40. The surgery to permanently implant the SCS device took place on May 17, 2019 at Danby Hospital in Danbury, Connecticut. The surgery was performed jointly by Dr. Kloth and Dr. Joshua Marcus (neurosurgeon). A representative from BSC named "Tanner" was also present to assist with the initial programming of the SCS device. Unfortunately, when "Tanner" turned

the device on for the first time Ms. Radice experienced an excruciating increase in her pre-operative pain to the point that she asked him to turn it off. "Tanner" then attempted to adjust the SCS device's programming. When he turned the device back on Ms. Radice again experienced a severe increase in her pain. The SCS device was again turned off and remained off until she returned home from the Hospital. The plan was to try to re-program it again at her next doctor visit.

41. Once home Ms. Radice turned the SCs device back on, but for a third time it produced severe pain from her low back up into the mid-back area where she had not previously experienced any pain. She continues to experience this mid-back pain to the present day.

42. On June 11, 2019 Ms. Radice attended her first post-operative visit with Dr. Kloth in his office in Danbury, Connecticut. A BSC representative was present as well. Again, the representative attempted to re-program the SCS device, installing three different types of programs to try to get better coverage of Ms. Radice's pain. Unfortunately, the results were again sub-optimal.

43. At her next visit with Dr. Kloth on July 2, 2019 Ms. Radice reported that she felt the SCS device was not cycling properly and when she used the higher levels of stimulation she experienced unwanted stimulation in her left flank and kidney area. She also reported that she had been feeling a sensation of "heat" or "burning" at the site of the IPG, which could occur at any time but was more prominent when using her charger. At times the IPG would become so hot that another person could actually touch the area and feel the heat through her skin. She also noticed that at times the charger would turn itself off after a few seconds because of excessive heat.

44. On July 30, 2019 Ms. Radice returned to Dr. Kloth's office for a further attempt at re-programing the device. The goal was to obtain better coverage of her pre-implantation pain and

eliminate the unwanted stimulation in the area of her left flank and kidney. With interrogation of the device the BSC representative determined that one of the leads—the left lead—had migrated away from its original location adjacent to the thoracic spine. X-rays performed on the same date confirmed that the left lead had migrated caudally one full vertebral body. A medical decision was made by Dr. Kloth to not perform lead revision surgery, but rather attempt again to re-program the problem away.

45. Two more attempts at re-programming the SCS device were performed by the BSC representative at Dr. Kloth's office on September 10, 2019 and September 24, 2019. Again they were unsuccessful. At that time Ms. Radice continued to experience the unwanted left flank/kidney stimulation as well as burning pain when using the SCS device at high amplitudes. On one occasion the pain became so intense that her husband drove her to the Stamford Hospital Emergency Room in Stamford, Connecticut for help. In his progress note of September 10, 2019 Dr. Kloth wrote the following with regard to the unplanned ER visit, which he shared with Ms. Radice:

> "She is upset and frustrated because her leads have migrated.... There is not much I can do about that, other than to try to program around the migration. Her being upset, frustrated, and anxious, leading her to be depressed and crying, is not a reason to go to the Emergency room. She has a chronic pain condition and she needs to try to deal with these ups and downs, when she is upset her pain will be worse."

Later in the same progress note Dr. Kloth added the following: "My concern (and this was also espoused by the Boston Scientific representative) nothing we are going to do is going to make her [Ms. Radice] happy".

46. On September 24, 2019, the SCS device was again re-programmed "at length" by the BSC representative. This latest re-programming included turning down the amplitudes to eliminate the burning pain that she was continuing to experience when using the device. The pain

that Ms. Radice experienced with one of the programs was so severe that it caused her to become incontinent with urine. Two times Ms. Radice involuntarily urinated while out in public.

47. Following the September 24, 2019 visit, and the latest attempt at re-programming the SCS device, Ms. Radice began to experience sudden unexpected "electrical shocks" when using the device. On one occasion, while lying in bed at approximately 3:00 a.m. Ms. Radice experienced a particularly intense shock extending from the site of the IPG up into the mid-back area and at the same time down into her leg. She yelled out in pain and cried for 20 minutes afterward. At approximately 5:00 a.m. the same morning she experienced another "shock", although not as severe as the first one. She found that the "shocks" would occur even if she turned the SCS device off. These occurrences were reported to Dr. Kloth at her next visit with him on October 22, 2019. Neither Dr. Kloth nor the BSC representative could offer any explanation for why this was happening. They again offered to re-program the device but this time Ms. Radice declined.

48. On December 23, 2019 Ms. Radice experienced on and off electrical shocks all day long. She asked her mother, who was with her at the time, to inspect her back. It appeared to her mother that Ms. Radice's back was swollen in the area of the IPG. At one point her mother touched the area of the IPG and felt an electrical shock with her fingers at the same time Ms. Radice felt it. Her mother told her that she needed to have the device taken out. Ms. Radice informed Dr. Kloth that she wanted to have the SCS device removed and Dr. Kloth in turn referred her back to Dr. Marcus for a second opinion.

49. On January 8, 2020 Ms. Radice saw Dr. Marcus in his office in Danbury, Connecticut. The History of Present Illness, as written by Dr. Marcus, states as follows:

> "Nicole returns today in follow-up. She is now over a year and a half out from placement of a spinal cord stimulator and pulse generator. She does

> not feel significant improvement in her left lower extremity sensitivity nor her back pain following implantation. Shortly after implantation there has been some inferior migration of the leads. She has a lot of complaints of pain secondary to battery [IPG] site. She feels the battery is moving and develops a lot of heat, soreness and itching around the battery insertion site. She also feels that her entire body can become "electrocuted" intermittently and without warning."

According to the progress note Dr. Marcus offered an option a surgical conversion from percutaneous leads to a paddle lead, but since would require a thoracic laminectomy, and there being no guarantee that it would improve Ms. Radice's condition, she opted instead to have the SCS device surgically explanted.

50. The surgery to explant the SCS device was performed by Dr. Marcus at the Danbury Hospital in Danbury, Connecticut on February 21, 2020. Ms. Radice took possession of the SCS device and leads after the surgery and maintains them in her possession at the present time.

51. The substantive law of the State of Connecticut applies to the claims asserted in this action.

COUNT I

STRICT LIABILITY UNDER THE CONNECTICUT PRODUCT LIABILITY ACT BASED ON THE DEFECTIVE MANUFACTURE OR CONSTRUCTION OF THE SCS DEVICE

52. Ms. Radice incorporates the allegations set forth in Paragraphs 1 through 51 above as if fully restated herein.

53. The State of Connecticut has enacted a statute to govern all product liability claims, including the claims set forth in this action. General Statutes §52-572m, et seq. (hereafter referred to as the "Product Liability Act" of "PLA"). §52-572m(b) defines a "product liability claim" as follows:

> "(b) "Product Liability Claim" includes all claims or actions brought for personal injury…caused by the manufacture, construction, design,

> formula, preparation, assembly, installation, testing, warnings and instructions, marketing, packaging, or labeling of any product". "Product Liability Claim" will include, but is not limited to, any action based on the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent."

54. The State of Connecticut has adopted Section 402A of the Restatement (Second) of Torts into its substantive law, including claims asserted under the PLA. See, e.g., *Vitanza v. The Upjohn Company*, 778 A.2d 829 (Conn. Supr. 2001); *Giglio v. Connecticut Light & Power Co.*, 429 A.2d 486 (1980).

55. Under Section 402A, as incorporated into the PLA, a product may be defective due to a flaw in the manufacturing process.

56. Under Section 402A, as incorporated into the PLA, a manufacturer of the product is strictly liable for injuries suffered if the product was sold in a defective condition unreasonably dangerous to the user and dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it.

57. BSC is and was at all times relevant to this action a "manufacturer" within the meaning of Section 52-572m(e) of the PLA.

58. BSC manufactured the SCS device for implantation into the human body.

59. The SCS device was defective and unreasonably dangerous when it left the hands of BSC and was implanted into Ms. Radice's body.

60. The SCS device was defective and unreasonably dangerous in that it deviated in a material way from the design specifications and/or performance standards approved by the FDA.

61. The SCS device was defective and unreasonably dangerous in that it deviated in a material way from other identical units from the same product line.

62. The SCS device was defective and unreasonably dangerous in that it wholly failed to deliver adequate or effective stimulation to address Ms. Radice's pain.

63. The SCS device was defective and unreasonably dangerous in that it significantly worsened Ms. Radice's pain when in use.

64. The SCS device was defective and unreasonably dangerous in that it improperly cycled itself causing unwanted and painful stimulation.

65. The SCS device was defective and unreasonably dangerous in that its battery component and/or electronic microcircuitry caused warmth/heat/burning at the site of the IPG.

66. The SCS device was defective and unreasonably dangerous in that the lead(s) migrated away from their original location causing unwanted stimulation in areas of the body that were not intended to be affected.

67. The SCS device was defective and unreasonably dangerous in that it aggravated or worsened Ms. Radice's pain complaints.

68. The SCS device was defective and unreasonably dangerous in that it intermittently and unexpectedly caused a sensation of "electrical shocks".

69. The aforementioned defects were beyond those which would have been contemplated by Ms. Radice or her physicians.

70. The SCS device was adulterated when it left the control of BSC within the meaning of 21 U.S.C. §§331 and 351.

71. The SCS device was defective and unreasonably dangerous in ways that were known or should have been known by BSC.

72. BSC is strictly liable to Ms. Radice in that it:

(a) manufactured and sold an adulterated product within the meaning of 21 U.S.C. §351;

(b) failed to establish and maintain procedures that would prevent the incorporation of nonconforming battery and lead components in the SCS device, as mandated by 21 C.F.R. §820.90;

(c) failed to take such action as needed to correct or prevent the incorporation of nonconforming battery and lead components in the SCS device, as mandated by 21 C.F.R. §820.100(a)(3);

(d) failed to establish and maintain quality control requirements over the suppliers of its battery and lead component parts, as mandated by 21 C.F.R. §820.50(2);

(e) failed to evaluate and select suppliers of its component parts on the basis of their ability to meet specified requirements, as mandated by 21 C.F.R. §850(a)(1);

(f) failed to develop, conduct, control, and monitor production processes to ensure that the SCS device conformed to the product specifications approved by the FDA, as mandated by 21 C.F.R. §870(a);

(g) failed to establish and maintain procedures to ensure that nonconforming manufacturing materials were removed during the manufacturing process, as mandated by 21 C.F.R. §870(h);

(h) failed to perform such inspections and tests or otherwise verify that its finished product (i.e., the SCS device) conformed to the specified requirements and performance standards approved by the FDA, as mandated by 21 C.F.R. §820.80; and,

(i) the SCS device was otherwise defective and unreasonably dangerous in its manufacture or construction as further discovery may demonstrate.

73. As a direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice has suffered serious and permanent bodily injuries and scarring.

74. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice was forced to undergo unnecessary surgeries.

75. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice has experienced pain and suffering, mental anguish, depression, anxiety, aggravation of her PTSD, and the loss of the enjoyment of life.

76. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice incurred past medical expenses and will likely incur medical expenses in the future.

COUNT II

STRICT LIABILITY UNDER THE CONNETICUT PRODUCT LIABILTY ACT BASED ON THE FAILURE TO PROVIDE ADEQUATE WARNINGS AND INSTRUCTIONS.

77. Ms. Radice incorporates the allegation set forth in paragraphs 1 through 76 above as if fully restated herein.

78. Section 52-572q(a) of the PLA provides as follows:

(a) A product seller may be subject to liability for harm caused to a claimant who proves by a preponderance of the evidence that the product was defective and that adequate warnings or instructions were not provided.

79. Section 402A of the Restatement (Second)of Torts, as incorporated into the PLA, provides that a product is defective and unreasonably dangerous when it is not accompanied by adequate warnings or directions as to its use.

80. BSC is and was, at all times relevant to this action, a 'product seller" within the meaning of the PLA.

81. BSC sold the SCS device for implantation into the human body.

82. The SCS device was defective and unreasonably dangerous when it left the hands of BSC and was implanted into Ms. Radice's body.

83. The SCS device was defective and unreasonably dangerous in that it was not accompanied by adequate warnings or instructions as to the risk or danger of wholly insufficient or ineffective stimulation; the risk or danger of warmth/heat/burning caused by the normal use of the device; the risk or danger of sudden and unexpected overstimulation, electrical shocks, and unwanted stimulation in areas not intended; and the risk or danger of the migration or repositioning of the surgically-placed lead(s).

84. BSC is strictly liable to Ms. Radice in that it:

(a) failed to adequately warn Ms. Radice of the SCS device's defective and unreasonably dangerous condition including the hazards associated with wholly ineffective or inadequate pain relief/stimulation; IPG warmth/heat/burning; sudden and unexpected over stimulation; electrical shocks and unwanted stimulation where not intended; and lead migration;

(b) failed to adequately warn Ms. Radice's physicians of the SCS device's defective and unreasonably dangerous condition including the hazards associated with ineffective or inadequate pain relief/stimulation; IPG warmth/heat/burning; sudden and unexpected over stimulation, electrical shocks and unwanted stimulation where not intended; and lead migration;

(c) failed to adequately warn Ms. Radice and her physicians of the aforementioned hazards as mandated by the FDA in 21 C.F.R. §801.109 and the Conditions of Approval imposed by the FDA for the commercial distribution of the SCS device;

(d) failed to correct or change its labeling, including the warnings/instructions, so as to adequately inform Ms. Radice and her physicians of the aforementioned hazards as mandated by the FDA in 21 C.F.R. §814.39 and §814.82(a)(9); and,

(e) otherwise failed to act in accordance with its "parallel" duty to warn Ms. Radice and her physicians under federal law as further discovery may demonstrate.

85. As a direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice has suffered serious and permanent bodily injuries and scarring.

86. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice was forced to undergo unnecessary surgeries.

87. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice has experienced pain and suffering, mental anguish, depression, anxiety, aggravation of her PTSD, and the loss of the enjoyment of life.

88. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice incurred past medical expenses and will likely incur medical expenses in the future.

COUNT III

NEGLIGENCE UNDER THE CONNETICUT PRODUCT LIABILITY ACT BASED ON THE DEFECTIVE MANUFACTURE OR CONSTRUCTION OF THE SCS DEVICE

89. Ms. Radice incorporates the allegations set forth in Paragraphs 1 through 88 above as if fully restated herein.

90. The State of Connecticut has enacted a statute to govern all product liability claims, including the claims set forth in this action. General Statutes §52-572m, *et seq*. §52-572(m)(b) defines a "product liability claim" as follows:

> "(b) "Product Liability Claim" includes all claims or actions brought for personal injury…caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings and instructions, marketing, packaging, or labeling of any product". "Product Liability claim" will include, but is not limited to, any action based on the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent."

91. BSC is and was at all times relevant to this action a "manufacturer" within the meaning of Section 52-572m(e) of the PLA.

92. BSC manufactured the SCS device for implantation into the human body.

93. The SCS device was unreasonably dangerous when it left the hands of BSC and was implanted into Ms. Radice's body.

94. The SCS device was defective and unreasonably dangerous in that it deviated in a material way from the design specifications and/or performance standards approved by the FDA.

95. The SCS device was defective and unreasonably dangerous in that it deviated in a material way from other identical units from the same product line.

96. The SCS device was defective and unreasonably dangerous in that it wholly failed to deliver adequate or effective stimulation to address Ms. Radice's pain.

97. The SCS device was defective and unreasonably dangerous in that it significantly worsened Ms. Radice's pain when in use.

98. The SCS device was defective and unreasonably dangerous in that it improperly cycled itself causing unwanted and painful stimulation.

99. The SCS device was defective and unreasonably dangerous in that its battery component and/or electronic microcircuitry caused warmth/heat/burning at the site of the IPG.

100. The SCS device was defective and unreasonably dangerous in that the lead(s) improperly migrated away from their original location causing unwanted stimulation in areas of the body that were not intended to be affected.

101. The SCS device was defective and unreasonably dangerous in that it aggravated or worsened M,. Radice's pain complaints.

102. The SCS device was defective and unreasonably dangerous in that it intermittently and unexpectedly caused a sensation of "electrical shocks".

103. The aforementioned defects were beyond those which would have been contemplated by Ms. Radice or her physicians.

104. The SCS device was adulterated when it left the control of BSC within the meaning of 21 U.S.C. §§331 and 351.

105. The SCS device was defective and unreasonably dangerous in ways that were known or should have been known by BSC.

106. BSC was negligent in that it:

(a) manufactured and sold an adulterated product within the meaning of 21 U.S.C. §351;

(b) failed to establish and maintain procedures that would prevent the incorporation of nonconforming battery and lead components in the SCS device, as mandated by 21 C.F.R. §820.90;

(c) failed to take such action as needed to correct or prevent the incorporation of nonconforming battery and lead components in the SCS device, as mandated by 21 C.F.R. §820.100(a)(3);

(d) failed to establish and maintain quality control requirements over the suppliers of its battery and lead component parts, as mandated by 21 C.F.R. §820.50(2);

(e) failed to evaluate and select suppliers of its component parts on the basis of their ability to meet specified requirements, as mandated by 21 C.F.R. §850(a)(1);

(f) failed to develop, conduct, control, and monitor production processes to ensure that the SCS device conformed to the product specifications approved by the FDA, as mandated by 21 C.F.R. §870(a);

(g) failed to establish and maintain procedures to ensure that nonconforming manufacturing materials were removed during the manufacturing process, as mandated by 21 C.F.R. §870(h);

(h) failed to perform such inspections and tests or otherwise verify that its finished product (i.e., the SCS device) conformed to the specified requirements and performance standards approved by the FDA, as mandated by 21 C.F.R. §820.80; and,

(i) was otherwise negligent in its manufacture or construction of the SCS device as further discovery may demonstrate.

107. As a direct and proximate result of BSC's negligence Ms. Radice has suffered serious and permanent bodily injuries and scarring.

108. As a further direct and proximate result of BSC's negligence Ms. Radice was forced to undergo unnecessary surgeries.

109. As a further direct and proximate result of BSC's negligence Ms. Radice has experienced pain and suffering, mental anguish, depression, anxiety, aggravation of her PTSD, and the loss of the enjoyment of life.

110. As a further direct and proximate result of the defective and unreasonably dangerous condition of the SCS device Ms. Radice incurred past medical expenses and will likely incur medical expenses in the future.

COUNT IV

NEGLIGENCE UNDER THE CONNECTICUT PRODUCT LIABILITY ACT BASED ON FAILURE TO PROVIDE ADQAUTE WARNINGS AND INSTRUCTIONS

111. Ms. Radice incorporates the allegation set forth in paragraphs 1 through 110 above as if fully restated herein.

112. Section 52-572q(a) of the PLA provides as follows:

(a) A product seller may be subject to liability for harm caused to a claimant who proves by a preponderance of the evidence that the product was defective and that adequate warnings or instructions were not provided.

113. BSC is and was, at all times relevant to this action, a 'product seller" within the meaning of the PLA.

114. BSC sold the SCS device for implantation into the human body.

115. The SCS device was defective and unreasonably dangerous when it left the hands of BSC and was implanted into Ms. Radice's body.

116. The SCS device was defective and unreasonably dangerous in that it was not accompanied by adequate warnings or instructions as to the risk or danger of insufficient or ineffective stimulation; the risk or danger of warmth/heat/burning caused by the normal use of the device; the risk or danger of sudden and unexpected overstimulation, electrical shocks, and unwanted stimulation in areas not intended; and the risk or danger of the migration or repositioning of the surgically-placed lead(s).

117. BSC was negligent in that it:

(a) failed to adequately warn Ms. Radice of the SCS device's defective and unreasonably dangerous condition including the hazards associated with ineffective or inadequate pain relief/stimulation; IPG warmth/heat/burning; sudden and unexpected over stimulation, electrical shocks and unwanted stimulation where not intended; and lead migration;

(b) failed to adequately warn Ms. Radice's physicians of the SCS device's defective and unreasonably dangerous condition including the hazards associated with ineffective or inadequate pain relief/stimulation; IPG warmth/heat/burning; sudden and unexpected over stimulation, electrical shocks and unwanted stimulation where not intended; and lead migration;

(c) failed to adequately warn Ms. Radice and her physicians of the aforementioned hazards as mandated by the FDA in 21 C.F.R. §801.109 and the Conditions of Approval imposed by the FDA for the commercial distribution of the SCS device;

(d) failed to correct or change its labeling, including the warnings/instructions, so as to adequately inform Ms. Radice and her physicians of the aforementioned hazards as mandated by the FDA in 21 C.F.R. §814.39 and §814.82(a)(9); and,

(e) was otherwise negligent as further discovery may demonstrate.

118. As a direct and proximate result of BSC's negligence Ms. Radice has suffered serious and permanent bodily injuries and scarring.

119. As a further direct and proximate result of BSC's negligence Ms. Radice was forced to undergo unnecessary surgeries.

120. As a further direct and proximate result of BSC's negligence Ms. Radice has experienced pain and suffering, mental anguish, depression, anxiety, aggravation of her PTSD, and the loss of the enjoyment of life.

121. As a further direct and proximate result of BSC's negligence Ms. Radice incurred past medical expenses and will likely incur medical expenses in the future.

WHEREFORE, Plaintiff Nicole Radice demands judgment in her favor and against the Defendant for the following:

(A) Compensatory damages for severe and permanent bodily injuries, pain and suffering, emotional distress, mental anguish, and the loss of the enjoyment of life;

(B) Past and future medical expenses;

(C) Attorneys' fees;

(D) Expert witness fees;

(E) Pre-and post-judgment interest;

(F) The costs of this action;

(G) Any other relief that the Court deems to be just and proper.

TYBOUT, REDFEARN & PELL

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